4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1952]

Seventh Annual Sentinel Initiative; Public Workshop; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; amendment of notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a public workshop entitled "Seventh Annual Sentinel Initiative" to be held on February 5, 2015. The workshop was announced in the <u>Federal Register</u> of October 22, 2014. This amendment reflects the addition of a <u>Comments</u> section and updates an incorrect Web site in the <u>Meeting Materials</u> section.

FOR FURTHER INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6358, Silver Spring, MD 20993, 301-796-3714, FAX: 301-847-3529, email:

SentinelInitiative@fda.hhs.gov.

## SUPPLEMENTARY INFORMATION:

In the <u>Federal Register</u> of October 22, 2014 (79 FR 63130), FDA announced that a public workshop entitled "Seventh Annual Sentinel Initiative" will be held on February 5, 2015.

1. On page 63131, in the second column, in the sixth line of the Meeting Materials section, the Web site "<a href="http://www.brookings.edu/health/events">http://www.brookings.edu/events</a>" is changed to read "http://www.brookings.edu/events".

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2. On page 63131, in the second column, a Comments section is added between the

Meeting Materials section and the Transcripts section to read:

"Comments: FDA is holding this public workshop to obtain information about a variety

of topics on active medical product surveillance. The deadline for submitting comments

regarding this public workshop is March 10, 2015.

Regardless of attendance in person or through the Web cast, interested persons may

submit either electronic comments to http://www.regulations.gov or written comments to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments.

Identify comments with the docket number found in brackets in the heading of this document.

Received comments may be seen in the Division of Dockets Management between 9 a.m. and

4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov."

Dated: November 20, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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